

COMPANY SANITIZED



**RHÔNE-POULENC INC.**

CN 7500, CRANBURY, NJ 08512-7500  
TELEPHONE: (609) 860-4000

October 29, 1992

(A)

PUBLIC NOTICE COPY

889200/4488  
8EHQ-92-12274

LIST ONLY

VIA FEDERAL EXPRESS

#3665214641

Document Processing Center (TS-790)  
Attn: Section 8(e) Coordinator (CAP Agreement)  
Office of Toxic Substances  
US Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS-408

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN 5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA.

This letter provides information on the following chemical substance:

Product Name:  
CAS Registry No.: Unknown

This report is being listed under the CAP pursuant to Unit II.B.I.c. of the CAP agreement and thus, no copies of the report are enclosed. The information was submitted previously to EPA under TSCA Section 8(e) by on November 28, 1983 (EPA Document Control Number 8EHQ-1283-0500 S). The title of the subject reports are:

Mutagenicity Evaluation of C-568 in the Ames *Salmonella*/Microsome Plate Test  
Mutagenicity Evaluation of C-568 in the Induced Mitotic Crossing Over, Reverse Mutation and Gene Conversion Assay in *Saccharomyces Cerevisiae* Strain D7  
Mutagenicity Evaluation of C-568 in the Mouse Lymphoma Forward Mutation Assay  
Mutagenicity Evaluation of C-568 in an *In Vitro* Sister Chromatid Exchange Assay in Chinese Hamster Ovary (CHO) Cells

mm  
2/16/95

The following is a summary of the adverse effects in this study:

The test material was positive in all assays. In the Ames Assay, an increase in revertants was observed in bacterial strains TA-1535 and TA-98 with and without metabolic activation. The test material also caused an increase in mitotic recombinants in the *saccharomyces cerevisiae* assay. In the mouse lymphoma assay, an increase in mutant frequencies was observed with and without metabolic activation. Significant increases in sister chromatid exchanges were seen in the CHO assay with and without metabolic activation.

RPI claims the specific chemical identity and the predecessor company's name as confidential business information. The chemical may be nonconfidentially identified as a "substituted polyglycidyl benzenamine".

RPI is submitting six copies of this cover letter. Three copies are stamped "Confidential Business Information" and have all confidential information underlined. The other three copies are stamped "Public Notice" and have all confidential information deleted.

#### SUBSTANTIATION OF CONFIDENTIALITY CLAIMS:

1. RPI asserts these claims on its own behalf and on behalf of its predecessors.
2. It is the intent that the specific chemical identity of this material and the linkage to RPI's predecessors be maintained as confidential on a permanent basis. This information is specific to the basics of our technology and to the science of specific chemical technology that is key to our business. The internal security procedures for guarding trade secret information from disclosure will be maintained on a permanent basis.
3. The information claimed as confidential has not been disclosed to the EPA or to any other governmental agency.
4. We have internal security systems in place to safeguard our proprietary information. Internal correspondence is kept secure, and access to our facilities is controlled at all times. Detailed information on the chemical structures of our products and research chemicals is restricted to only those technical and regulatory personnel who need this knowledge to carry out their employment duties. Employees who have this information are told of its confidentiality proprietary nature and of the need to protect against its disclosure. These security measures will continue in the future.
5. No one outside the company or its predecessor companies has access to the confidential information cited in this claim.
6. The information claimed as confidential has not appeared in any advertising or promotional materials, material safety data sheets or similar materials, professional or trade publications, or any other publicly available publications.
7. The EPA, other federal agencies, or court have not made any confidentiality determination regarding the information associated with this chemical substance.
8. Disclosure of this confidential information would allow a competitor to immediately determine the chemical identity. This would cause a premature loss of our business to the

3

competitor. Should this happen, incentives to develop new products would be stifled and would reduce the competitive strength of our own and our customers' industries.

9. This substance has not been patented in the USA or elsewhere and there is not a patent pending.

10. This substance was an R&D substance and may be sold commercially at some point.

11. A competitor could analyze the chemical, but would have to obtain a sample. This would be difficult in view of the measures taken to restrict availability to only those directly involved in its R&D, manufacture and use. Analysis of the chemical may be possible using modern analytical techniques at considerable expense.

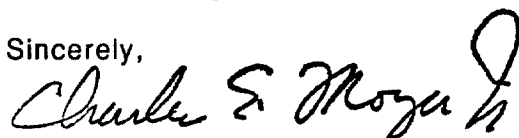
12. The disclosure of the information we claim as CBI could lead to the identification of confidential processes used to synthesize and manufacture the substance.

13. The CAS Registry Number for this product is unknown at this time.

14. This substance is not subject to any FIFRA regulation or reporting.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology, at 919-549-2222 (Rhône-Poulenc, P. O. Box 12014, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,



Charles E. Moyer, Jr., Ph.D.  
Director, Product Safety  
(609) 860-3589



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Charles E. Moyer, Jr., Ph.D.  
Director, Product Safety  
Rhône-Poulenc Inc.  
CN 7500  
Cranbury, New Jersey 08512-7500

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*

Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12274A



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### Triage of 8(e) Submissions

Date sent to triage: 8/24/95

NON-CAP

CAP

Submission number: 12274A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

#### For Contractor Use Only

entire document: 0 1 2 pages 1,2,3 pages 1,2,3

Notes:

Contractor reviewer: POK Date: 3/21/95

## CECATS/TRIAGE TRACKING DBASE ENTRY FORM

## CECATS DATA:

Submission # 8EHQ-1092-122745 SEQ. ATYPE INT SUPP FLWPSUBMITTER NAME: Rhone - Pol. enc  
Inc.

## INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

## DISPOSITION:

0639 REFER TO CHEMICAL SCREENING0678 CAP NOTICE

## VOLUNTARY ACTIONS:

0401 NO ACTION REPORTED

0402 STUDIES PLANNED/IN PROGRESS

0403 NOTIFICATION OF WORKER RIGHTS

0404 LABEL/MSDS CHANGES

0405 PROCESS/HANDLING CHANGES

0406 APP/USE DISCONTINUED

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

SUB. DATE: 10/29/92 OTS DATE: 10/29/92 CSRAD DATE: 02/16/95

## CHEMICAL NAME:

C-568Benzenamine, substituted Poly glycidyl

## CAS#

confident

"

per 8ehq-1283-0500

## INFORMATION TYPE:

## P F C

0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
<u>0204</u>	MUTA (IN VITRO)	<u>01 02 04</u>
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

## INFORMATION TYPE:

0216	EPI/CLIN
0217	HUMAN EXPOS (PROD CONTAM)
0218	HUMAN EXPOS (ACCIDENTAL)
0219	HUMAN EXPOS (MONITORING)
0220	ECO/AQUA TOX
0221	ENV. OCC/REL/FATE
0222	EMER INCI OF ENV CONTAM
0223	RESPONSE REQUEST DELAY
<u>0224</u>	PROD/COMP/CHEM ID
0225	REPORTING RATIONALE
0226	CONFIDENTIAL
0227	ALLERG (HUMAN)
0228	ALLERG (ANIMAL)
0239	METAB/PHARMACO (ANIMAL)
0240	METAB/PHARMACO (HUMAN)

## P F C

01 02 04
01 02 04
01 02 04
01 02 04
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01 02 04
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01 02 04
01 02 04
01 02 04

## INFORMATION TYPE:

0241	IMMUNO (ANIMAL)
0242	IMMUNO (HUMAN)
0243	CHEM/PHYS PROP
0244	CLASTO (IN VITRO)
0245	CLASTO (ANIMAL)
0246	CLASTO (HUMAN)
0247	DNA DAM/REPAIR
0248	PROD/USE/PROC
0251	MSDS
0299	OTHER

## P F C

01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04
01 02 04

## TRIAGE DATA:

## NON-CBI INVENTORY

YES

CAS SR

NO

IN P/AMINI

## ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

## SPECIES

In Vitro

## TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

## USE:

## PRODUCTION:

109212 Behq-1283-05005

4) 8EHQ-92-12274: Rank - medium.

Chemical: substituted polyglycidyl benzeneamine (C-568: CAS# unknown).

Letter from Rhone-Poulenc Inc., Cranbury NJ, dated October 29, 1992: Positive for gene mutations in the Salmonella/Ames assay in strains TA98 and TA1535 both without and with metabolic activation.

Positive for gene mutations in Saccharomyces cerevisiae strain D7.

Positive for gene mutations in L5178Y TK<sup>+</sup>/<sub>-</sub> mouse lymphoma gene mutation assay in vitro both without and with metabolic activation.

Positive for DNA effects (mitotic crossing over and recombination) in Saccharomyces cerevisiae in strain D7.

Positive for DNA effects (sister chromatid exchanges: SCEs) in Chinese hamster ovary (CHO) cells in vitro both without and with metabolic activation.